EGETIS THERAPEUTICS

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Investor and Analyst conference call

29th of June 2023

Site activation in the pivotal ReTRIACt trial for Emcitate® and updated timeline for the US NDA submission

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Agenda for today

1. Site activation in the pivotal ReTRIACt trial for Emcitate® and updated timeline for the US NDA submission
   - Emcitate regulatory pathway to submissions in EU and US
   - ReTRIACt trial – design and timelines

2. Q&A

Company participants at today's call

Nicklas Westerholm
CEO

Christian Sonesson, PhD
VP Product Strategy & Development

Karl Hård, PhD
VP IR, Communications & Business Development

Kristina Sjöblom Nygren, MD
CMO

Site activation in the pivotal ReTRIACt trial for Emcitate® and updated timeline for the US NDA submission

June 28, 2023

Company to host a webcast at 3.00 pm CEST (9.00 am EDT) tomorrow June 29

Stockholm, Sweden, June 28, 2023. Egetis Therapeutics AB (publ) (Nasdaq Stockholm: EGTX) today announced that the first site has been activated in the pivotal ReTRIACt clinical trial for the new drug application (NDA) in the USA for *Emcitate*. The Company further announced that it now expects topline results from the ReTRIACt study during the first half of 2024 and estimates subsequent NDA submission in the USA in mid-2024, under the fast-track designation. The updated timelines are due to the substantial delay in the study start, and an anticipated higher number of treatment naive patients, which implies a longer trial duration per patient, expected to be recruited in the trial, compared to the original assumptions. As a consequence of the delay, the build-up of the commercial infrastructure in the US will be aligned with the updated NDA submission timelines and all resources will be focused on the *Emcitate* ReTRIACt study and the upcoming EU submission. Therefore, the in-house development of *Aladote* will be parked, until *Emcitate* submissions have been completed.

Emcitate regulatory pathway to submissions in EU and US

The first potential treatment for MCT8 deficiency, an ultra rare genetic disease with high unmet medical need and no available treatment

Included in MAA in EU in early autumn 2023

Included in NDA in US mid 2024 under the Fast Track Designation

Not required for MAA or NDA submissions

Triac Trial I

- Completed 2018 (Groeneweg, 2019)
- Open-label, international, multi-centre study
- N= 46

EMC cohort study

- New data 2021 (van Geest, 2022)
- N= 27 from Triac Trial I & N= 40 new pts from compassionate use

Natural history

- Retrospective data, 2003 to 2019 (Groeneweg, 2020)
- N= 151

ReTRIACt Trial (Controlled study)

- N= 16
- Placebo controlled
- Top line results H1 2024

Triac Trial II

- Open-label, international, multi-centre study
- Pts ≤ 30 months of age
- Focus on neurocognition
- N= 22
- Full 96 weeks data, expected mid 2024

Data already available

Current status of ReTRIACt and updated timelines

- First site activated in the pivotal ReTRIACt trial
- The timelines for completion of ReTRIACt updated to first half 2024 due to:
  1) The substantial delay in the study start
  2) An anticipated higher number of treatment naive patients expected to be recruited in the trial compared to the original assumptions
  3) Lower-than-expected recruitment capacities per month at the participating sites

Disease awareness initiatives are bearing fruit

- Awareness of MCT8 deficiency remains low also among specialists, with a high proportion of patients living without correct diagnosis
- Increasing disease awareness and facilitating diagnostic testing are key strategic imperatives for 2023
- Over 40 new patients identified in the US only this year
- Emcitate is presently being supplied on a named patient basis, following individual approval from the national regulatory agencies, to
  - around **180** patients
  - in over 25 countries
- An Expanded Access Program has been approved in the US, allowing access to Emcitate for patients that *do not meet the inclusion criteria in ongoing clinical trials in the US*

DISEASE AWARENESS AND EDUCATION

COLLABORATION WITH PAGs & KOLs

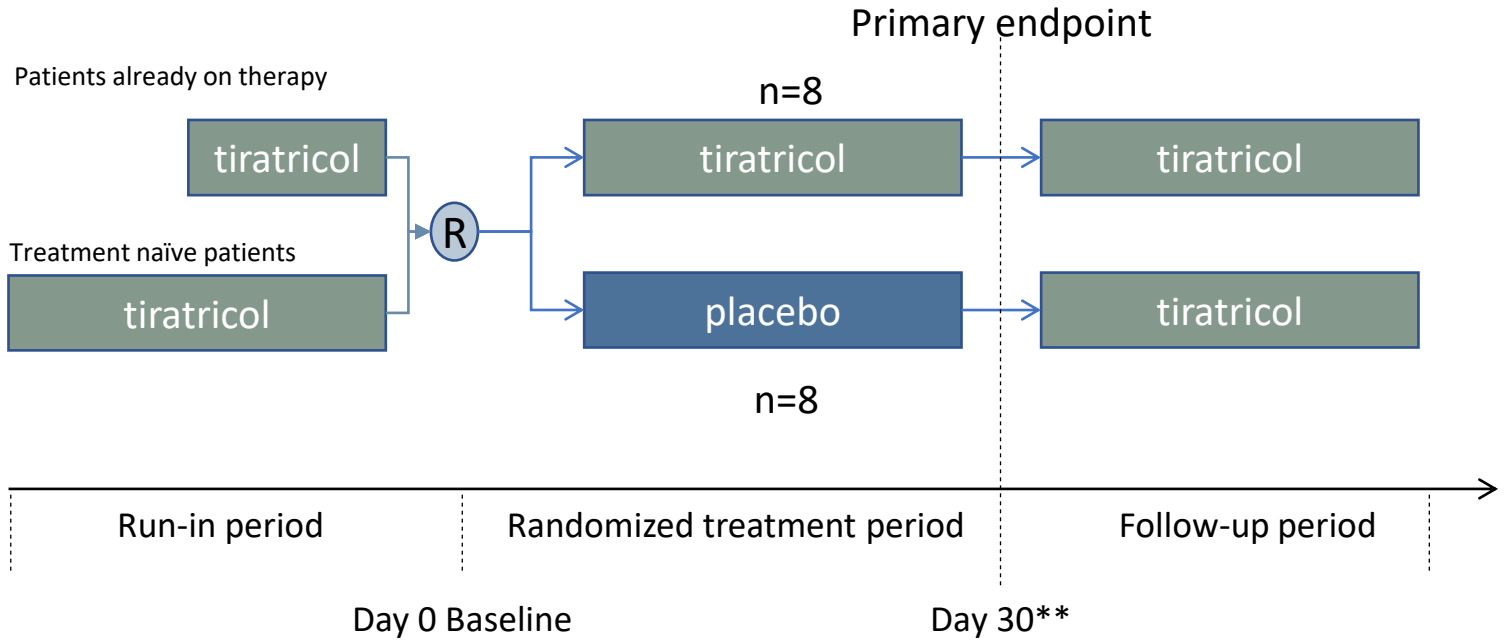
EXHIBIT AT SCIENTIFIC/MEDICAL CONFERENCES

Increasing number of previously undiagnosed and treatment naïve patients are being identified

ReTRIACt – A randomised placebo-controlled withdrawal study designed to show an effect on the proportion of patients needing rescue treatment

Verifying previous results in single arm Triac Trial I and a real-world cohort study

- A 30-day, placebo-controlled withdrawal study in 16 treated patients, to **verify the results on T3** levels seen in previous clinical trial and publications - but in a randomized **controlled** setting
- Design agreed with FDA (no change)
- The study allows for inclusion of both patients that are already on therapy, as well as patients that are previously treatment naïve
- Treatment naïve patients require a longer run-in period to stabilize T3 levels around normal range before randomization
- Thus, a higher proportion of treatment naïve patients will lead to an extended study duration.
- Based on the new timelines for study completion, an **NDA** in the US is targeted to be submitted in **mid 2024** under the Fast Track Designation.



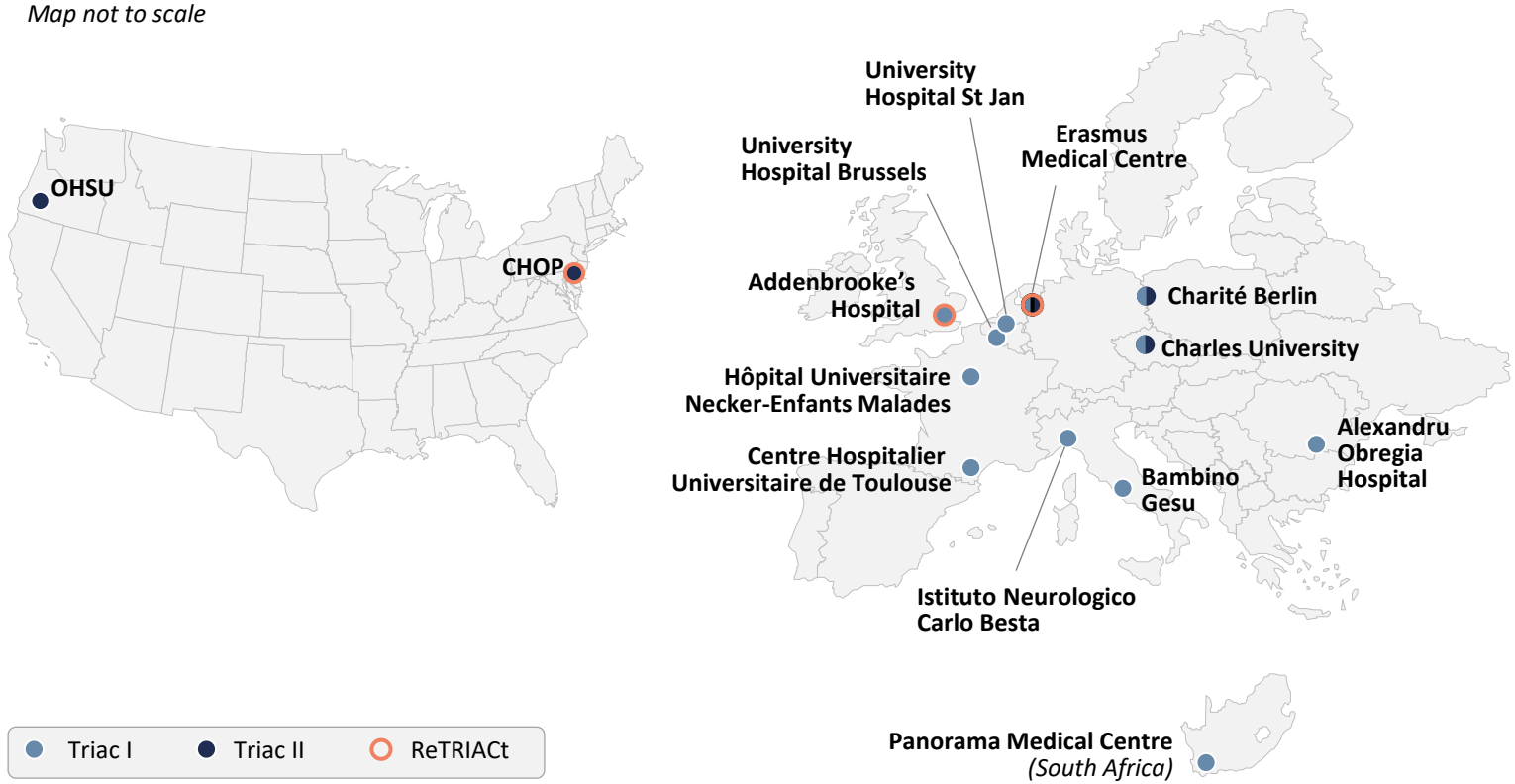
Primary endpoint: Proportion of participants who meet the rescue criterion (T3>ULN*) during the 30-day double-blind randomized treatment period

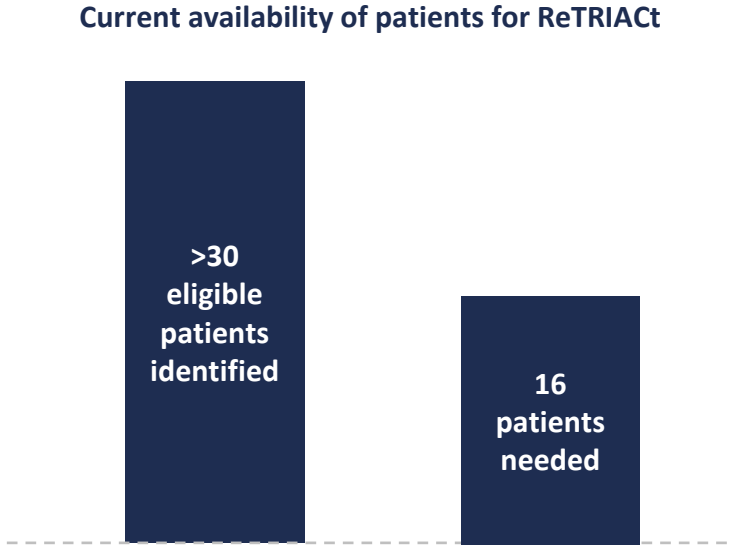
* ULN: Upper Limit of Normal

** Randomized treatment period ends after 30 days or when rescue criterion (T3 >ULN) is met, whichever comes first

Availability of patients at study sites in ReTRIACt

Map not to scale





All 3 sites in ReTRIACt used in prior Triac Trial I and/or ongoing Triac Trial II

Triac I study sites include: Addenbrooke's Hospital (Cambridge, UK), Alexandru Obregia Hospital (Bucharest, Romania), Bambino Gesu (Rome, Italy), Centre Hospitalier Universitaire de Toulouse (Toulouse, France), Charité Berlin (Berlin, Germany), Charles University (Prague, Czech Republic), Erasmus Medical Centre (Rotterdam, Netherlands), Hôpital Universitaire Necker-Enfants Malades (Paris, France), Istituto Neurologico Carlo Besta (Milan, Italy), Panorama Medical Centre (Panorama, South Africa), University Hospital Brussels (Brussels, Belgium) and University Hospital St Jan (Brugge, Belgium).
Triac II study sites include: Children's Hospital of Philadelphia (Philadelphia, Pennsylvania), Charité Berlin (Berlin, Germany), Charles University (Prague, Czech Republic), Erasmus Medical Centre (Rotterdam, Netherlands) and OHSU (Portland, Oregon).
ReTRIACt study sites include: Addenbrooke's Hospital (Cambridge, UK), Children's Hospital of Philadelphia (Philadelphia, Pennsylvania) and Erasmus Medical Centre (Rotterdam, Netherlands).

Focus on the Emcitate ReTRIACt study and EU & US submissions

Implications

- All resources will be focused on the Emcitate ReTRIACt study and the upcoming EU submission
- The build-up of the commercial infrastructure in the US will be aligned with the updated NDA submission timelines
- In-house development of Aladote will be parked until Emcitate submissions have been completed.

Upcoming pipeline milestones

Emcitate®

2022

- ✓ US & EU ODD RTH-b
- ✓ Recruitment completed in Triac Trial II, Q2 2022

2023

- FPI ReTRIACt for US NDA
- Filing EU MAA early autumn ‘23

2024/25

- Results ReTRIACt for US NDA
- Filing US NDA mid ‘24 under Fast Track Designation
- Results Triac Trial II
- EU approval and launch
- US approval and launch
- US Rare Pediatric Disease Priority Review Voucher

Q&A